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ASSEMBLY/STERILIZER FACILITY FEASIBILITY PROGRAM QUARTERLY PROGRESS REPORT NO. 5

GENERAL ELECTRIC

RE-ENTRY SYSTEMS DEPARTMENT

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QUARTERLY PROGRESS REPORT NO. 5

21 JULY TO 21 OCTOBER 1966

CONTRACT NO. NAS 1-5381

PREPARED FOR

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SECTION I

SUMMARY

I. SUMMARY

This is the fifth Quarterly Progress Report submitted under NASA contract NAS 1-5387. This report describes the activities and accomplishments on the program from 21 July 1966 to 21 October 1966.

The major accomplishments of the period were:

- Continuing checkout and rework of the Assembly/Sterilizer Analog
- Revision of the sterility verification cycle
- Completion of first sterility verification cycle and collection of bio-assay data related thereto

Due to difficulties in the check-out and preparation of the Assembly/Sterilizer Analog, performance of the test program and demonstration, and the supporting bio-assay has been delayed. These activities have been initiated and are in progress at the close of the quarter. The delays have necessitated that an extension of program completion date to 21 February 1967 be requested. GE has requested this extension from the NASA/LRC Contracting officer.

As a result of the delays, the primary weight of effort by GE during the quarter has been on the GE funded support of the program in providing a working analog for the test program. This has caused a minimal level of NASA funded effort throughout most of the quarter. This report summarizes the quarter's activities. A more detailed discussion will be contained in the final report wherein the significance of this quarter's efforts can be evaluated in context with the test program.

SECTION II

PROGRAM STATUS

II. PROGRAM STATUS

II-1 PROGRAM TASKS

TASK 1. TEST SAMPLE

This effort was completed during the third quarter of the program.

TASK 2. TEST PROGRAM AND DEMONSTRATION

A. TEST PLAN

The test plan was completed in the second quarter of the program. Events during this quarter have indicated the advisability of the following changes:

1. Delete the use of ETO/FREON in the main chamber (See also Section IV)

2. Modify the assay procedure for the stainless steel sterility control specimens (See also Task 3)

The first of these changes requires modification of the sterility verification and demonstration cycles. The revised sterility verification test cycle is shown in Table II-1 and Fig. II-1. The revision of demonstration cycle descriptions is in progress.

The modified assay procedure is outlined under the Task 3 discussion below.

B. ASSEMBLY/STERILIZER ANALOG INSTALLATION

The Assembly/Sterilizer Analog installation was completed in the fourth program quarter.

C. OPERATION OF THE ASSEMBLY/STERILIZER ANALOG

During the first half of the quarter, the checkout and rework of the system continued to identify and correct deficiencies and transportation induced damage. A sterility verification cycle was attempted but it was found that the main chamber blower would not handle ETO/FREON (See Section IV).

After revision of the test plan, the checkout and operation was resumed and a successful sterility verification cycle was performed during the latter part of the quarter. The results from this cycle are described under Task 3 below.

D. MANIPULATION TESTS

No further effort has been expended on the manipulation tests during this quarter.

TABLE II-1 - STERILIZATION VERIFICATION CYCLE

Step	Time Hr.	Description	Duration Hr.
1.	0	Prepare A/S Analog	4
2.	4	Heat decontaminate Main Chamber	21
3.	18 3/4	Place 40 specimens in auxiliary chamber (Groups A, B, and C)	1/4
4.	19	ETO decontaminate auxiliary chamber	6
5.	22	Prepare bio-assay materials	2
6.	24	Sterilize bio-assay materials in autoclave	1
7.	25	Transfer all specimens from the auxiliary chamber to the main chamber and bio-assay material from autoclave to main chamber - do not seal doors	1/4
8.	25 1/4	Assay group A specimens (10)	1/2
9.	25 3/4	Remove group A specimens from main chamber and put them in autoclave	1/4
10.	26	Open Group B and remove 5 specimens	1/4
11.	26 1/4	Assay 5 specimens from Group B and place them in the autoclave	1/2
12.	26 3/4	Open Group C and remove 5 specimens	1/4
13.	27	Return the remainder of group C (out of the container) to the auxiliary chamber and seal	1/4
14.	27 1/4	Assay 5 specimens from Group C and place them in the autoclave	1/2
15.	27 3/4	Seal inner autoclave door and remove assayed specimens	1/2
16.	28	Lay out specimens from Group B in main chamber	1/4
17.	28 1/4	Sterilize auxiliary and main chambers	36
18.	61 1/4	Prepare bio-assay material	2

TABLE II-1 Continued

19.	63 1/4	Sterilize bio-assay material in autoclave	1
20.	64 1/4	Transfer bio-assay material to main chamber & seal autoclave	1/4
21.	64 1/2	Sterilize 10 specimens (Group D) in autoclave	1
22.	64 1/2	Assay Group B specimens	1/2
23.	65	Transfer group C to main chamber and assay group C specimens	1/2
24.	65 1/2	Transfer Group D specimens from autoclave to main chamber	1/4
25.	65 3/4	Assay Group D specimens	1/2
26.	66 1/4	Remove all contents from main chamber through autoclave - do not open outer door till inner door is sealed	1/2
27.	66 3/4	End of test.	

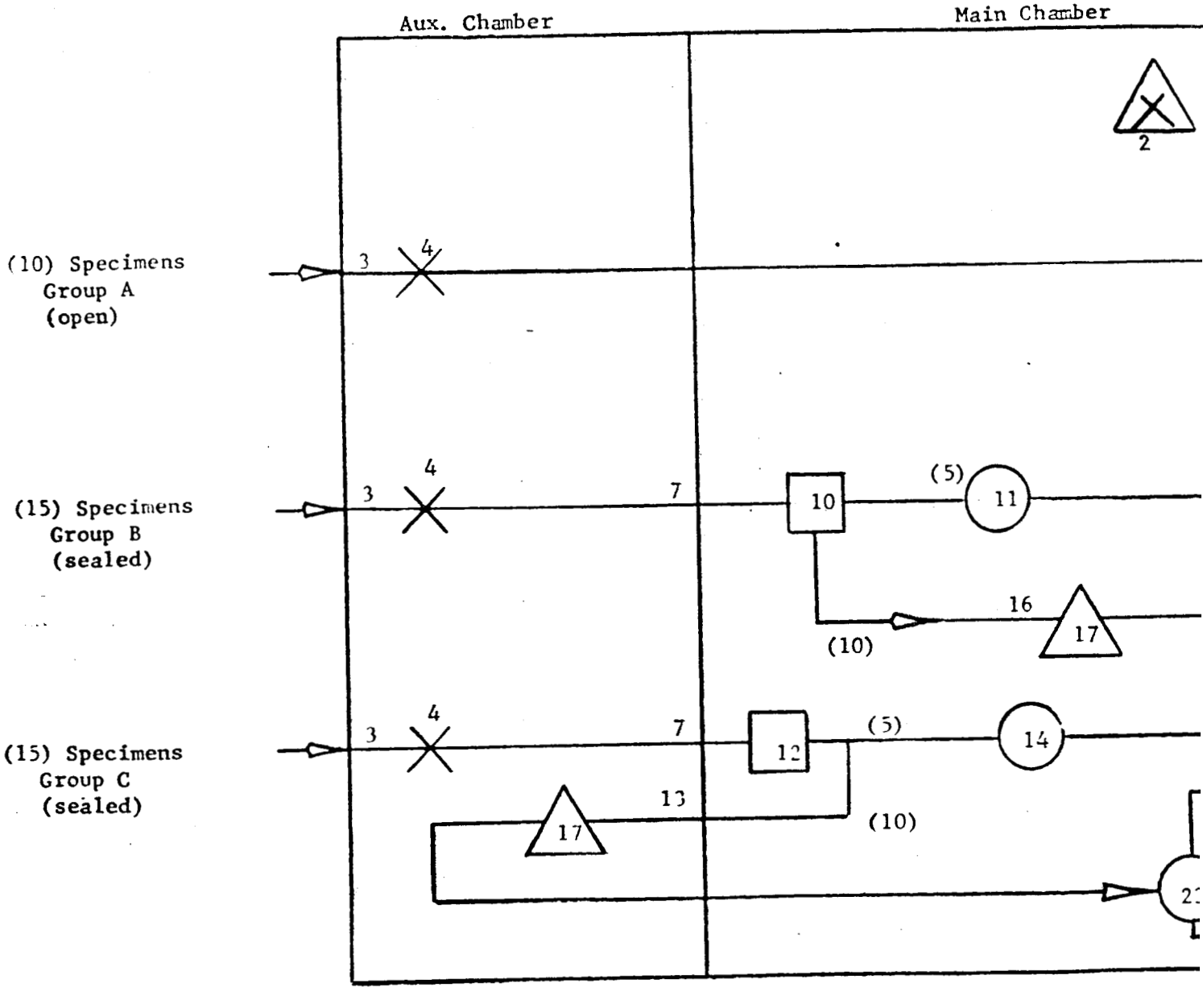
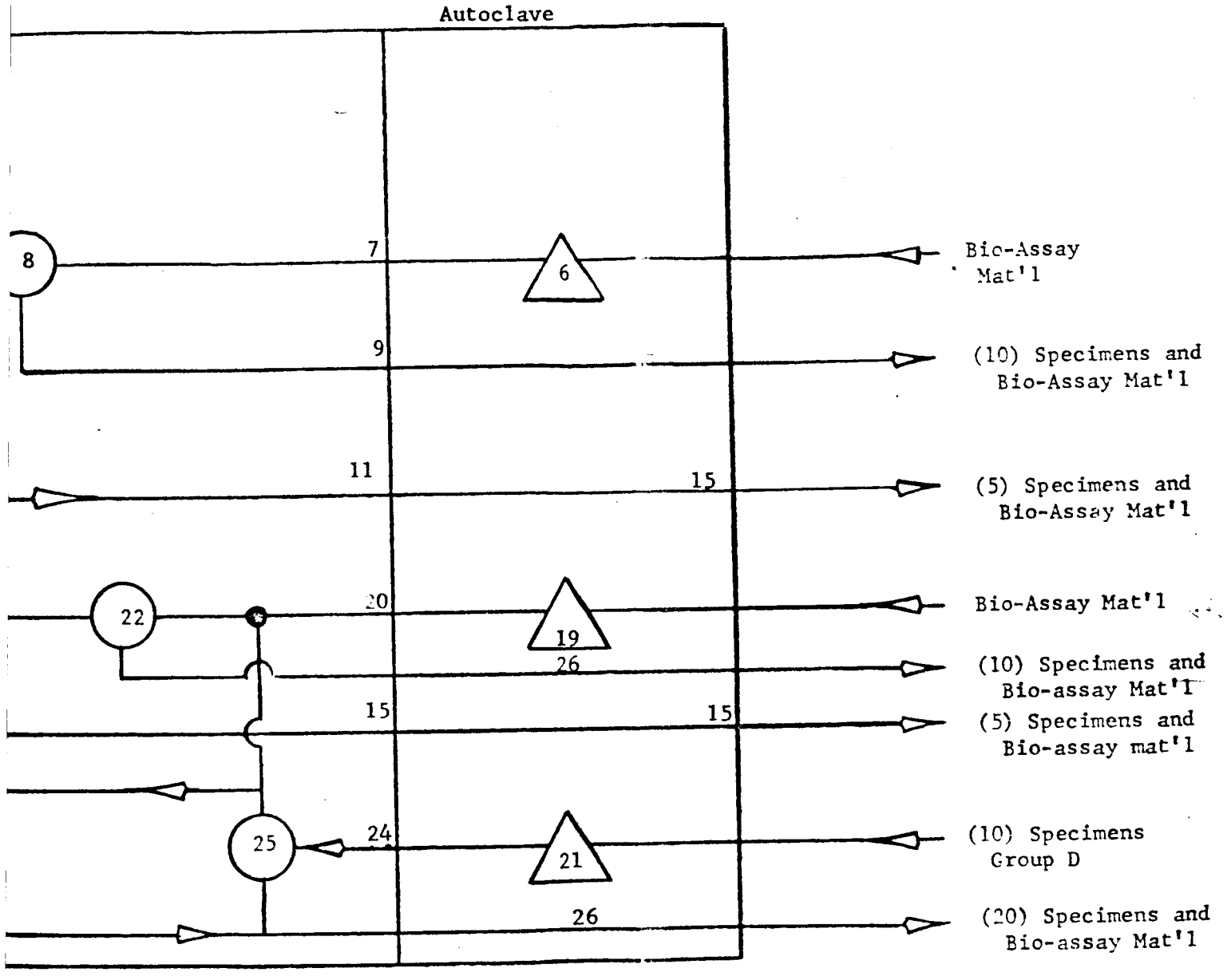

Aux. Chamber
Main Chamber
(10) Specimens
Group A
(open)
(15) Specimens
Group B
(sealed)
(15) Specimens
Group C
(sealed)
2
3
4
7
10
(5)
11
16
17
(10)
12
14
13
Decontaminate - ETO
Decontaminate - Dry Heat
Open Container
Sterilize
Assay

FIGURE II-1



NOTE: (1) Numbers in parentheses are specimen quantities - other numbers are step numbers.

(2) Specimen groups A, B, & C seeded with B. subtilis var. niger; group D seeded with B. stearothermophilus

RILITY VERIFICATION CYCLE FLOW DIAGRAM

TASK 3. BIO-ASSAY

A. BIO-ASSAY PLANNING

The bio-assay planning was completed with the issue of the test plan in the second program quarter. However, the assays performed in support of the test work of Task 2 have shown excessive sensitivity (i.e. populations too numerous to count) when plating the strip and the peptone diluent remaining after drawing off the 1.0 ml and 0.1 ml aliquots. Thus the procedure will be modified to plate the remaining peptone in 5 ml aliquots.

B. BIO-ASSAY PERFORMANCE

1. TEST SAMPLE

Five wired test sample printed circuit boards (SN 8, 19, 38, 51 and 56) were assayed to define the pre-test condition for the test cycles of Task 2. With the exception of SN 56, the total reduced count was 11 aerobic non-heat-shocked organisms on four samples with a total surface area of about 80 square inches. (NOTE: These numbers reflect lower counts than shown in the thirteenth monthly report due to correction of a data reduction error.) This gives an average surface count of 20 organisms per square foot. Culturing of the aliquots from SN 56 resulted in populations too numerous to count. It was suspected that this result was due to contamination in the laboratory by an organism used in massive quantities in the bio-laboratory. The data from the assay is contained in Table II-2.

TABLE II-2. ASSEMBLED PRINTED CIRCUIT BOARD

MICROBIOLOGICAL ASSAYS
(Notes 1 & 2)

Sample Serial No.	Non-Heat Shocked		Heat Shocked		Plated Parts Aerobic Non-Heat Shocked
	Aerobic	Anerobic	Aerobic	Anaerobic	
8	1 (5)	0	0	0	0
19	1 (5)	0	0	0	0
38	0	0	0	0	0
51	0	0	0	0	1
56	TNTC	0	TNTC	0	TNTC
CONTROL	0	0	0	0	0

NOTES: 1. Control Samples on Anaerobic incubation

C sporogenes	Pos.
A faecalis	Neg.

2. The numbers 1 (5) represent a count of one in a 20% aliquot giving a reduced count of 5.

Analysis of the growth from the assay of sample SN 56 has shown it to be morphologically identical with B. subtilis var. niger which, during the period of these assays, was being used in massive quantities in the biological laboratory. Thus, this growth is attributed to laboratory contamination of the specimen.

2. TEST PROGRAM ASSAY OF TEST SPECIMENS

a) Aborted Sterility Verification Cycle

Although the first attempted sterility verification cycle was aborted due to equipment malfunction, the test specimens which were in the analog were assayed. These results, which are presented below, are very sporadic because the specimens were not exposed to the proper ETO/FREON treatment.

Auxiliary Chamber		Main Chamber	
Number of Specimens	Number of Logs of Kill	Number of Specimens	Number of Logs of Kill
2	>9	1	10^8
2	8	1	10^5
2	6	3	$<10^7$
1	<7	2	$<10^6$
1	<6	3	$<10^4$
2	<4		

b) First Complete Sterility Verification Cycle

The assay of the first sterility verification cycle called for the following (refer to Table II-1 and Figure II-1):

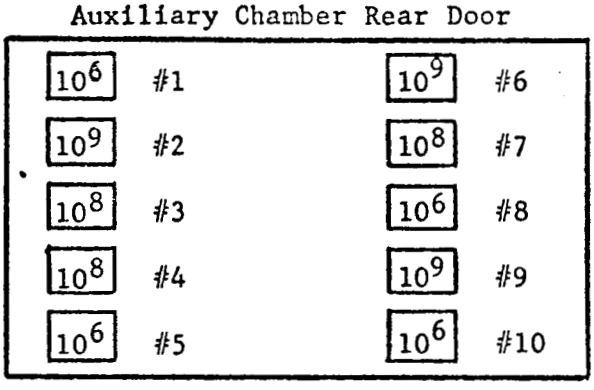
- Assay of 10 specimens (Group A) to determine the effectivity of the ETO/FREON decontamination in the Auxiliary chamber.
- Assay of 5 specimens from each of two groups (Band C) to determine if any inadvertent decontamination of these specimens occured during their exposure, in sealed containers, to the ETO/FREON treatment in the auxiliary chamber.
- Assay of 10 specimens (Group C) to determine the efficacy of the dry heat sterilization in the auxiliary chamber.
- Assay of 10 specimens (Group B) to determine the efficacy of the dry heat sterilization in the main chamber.

- Assay of 10 specimens (Group D) to determine the efficacy of the wet heat sterilization in the autoclave.

The specimens of groups A, B, and C were seeded with B. subtilis var. niger and those of group D were seeded with B. stearothermophilus.

Group A specimens were arranged in the auxiliary chamber as shown in Figure II-2. The numbers in the blocks indicate the nominal pre-treatment populations.

FIGURE II-2. Group A Arrangement During ETO/FREON Treatment



The results of the Assay of Group A are given in Table II-3.

TABLE II-3. GROUP A ASSAY RESULTS

Specimen #	Plated Specimen (Note 1)	Plated Aliquots 1.0 ml	0.1 ml
1	TNTC	2	2
2	TNTC	1	2
3	TNTC	22	2
4	TNTC	26	19
5	TNTC	0	2
6	6	1	2
7	TNTC	0	1
8	LOST THROUGH BREAKAGE		
9	0	0	0
10	1	0	1

NOTE: 1. The remaining peptone dilution fluid and the stainless steel strip.

The results of the assay of the five specimens from each of Group B and C are shown in Table II-4.

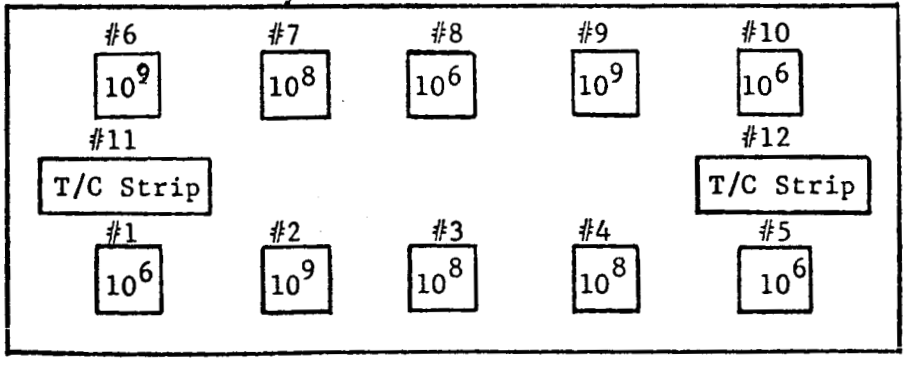
TABLE II-4. Group B and C Assay Results Of Inadvertent ETO/FREON Decontamination

Group	Specimen #	Population Pretreatment (nominal)	Post treatment
B	11	10^6	60,000
	12	10^6	31,000
	13	10^8	19,000,000
	14	10^8	19,000,000
	15	10^9	60,000,000
C	16	10^6	15,000
	17	10^6	15,000
	18	10^8	1,500,000
	19	10^9	1,500,000
	20	10^9	1,500,000

The reduction of population of these specimens resulted from container seal leaks; steps have been taken to prevent repetition of this problem.

The specimens of group B exposed to the dry heat sterilization treatment were arranged in the main chamber as shown in Figure II-3. The assay of these specimens (post sterilization) showed no growth in a seven day incubation period.

FIGURE II-3. Group B Arrangement During Dry Heat Sterilization



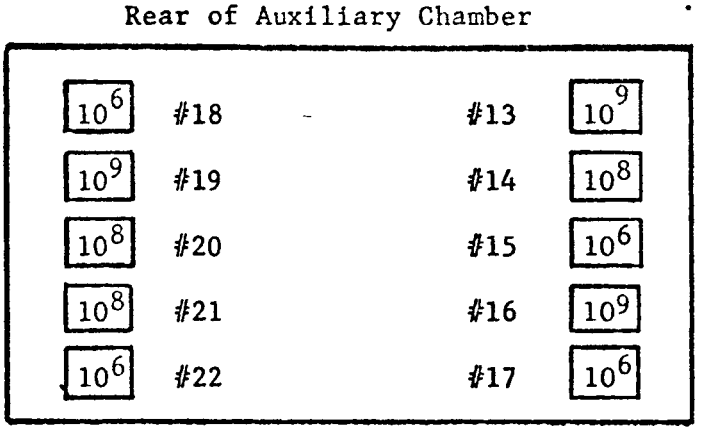
FRONT OF MAIN CHAMBER

NOTE: 1. T/C strips had Iron Constantan thermocouples attached.

2. Numbers in blocks are nominal pre-treatment population.

The specimens of Group C exposed to the dry heat sterilization treatment were arranged as shown in Figure II-4. The assay of these specimens (post sterilization) showed no growth in a seven day incubation period.

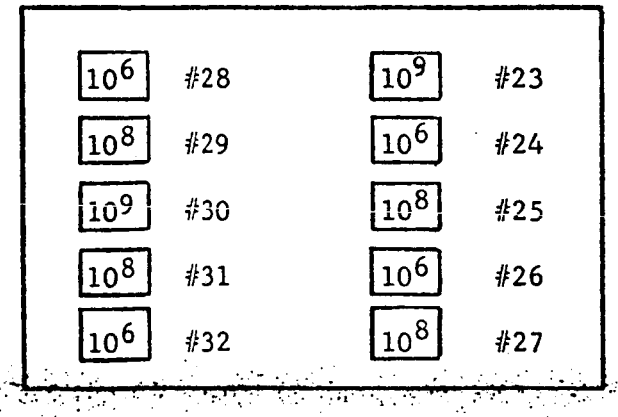
FIGURE II-4. Group C Arrangement During Dry Heat Sterilization



NOTE: Numbers in blocks are nominal pre-treatment population

The specimens of group D were exposed to wet heat sterilization in the autoclave. They were arranged as shown in Figure II-5. The assay of the specimens (post sterilization) showed no growth in a seven day incubation period.

FIGURE II-5. Group D Arrangement During Wet Heat Sterilization



NOTE: The numbers in the blocks are nominal pre-treatment population

C. Test Specimen Preparation

Preparation of test specimens was completed last quarter except for the B. stearothermophilus specimens with a nominal population of 10^9. The preparation of these specimens was completed this quarter. The maximum viable population which has been demonstrably achieved is 4×10^8. The spore suspension was prepared and harvested according to the test plan. When sporulation was microscopically 90 percent complete, direct counts on the number of spores was determined with a Petroff Hauser counting chamber. The results indicated a spore count of 5.5×10^{11}. However, when a viable count was made a concentration of 4.6×10^8 viable spores was found. This appears to be the highest concentration of spores which it is practical to prepare on a test specimen of this type, based on a viable count. 50 stainless steel strips were prepared using the spore counts obtained in the Petroff Hauser chamber. The inoculum was 2.75×10^9 spores per strip. Four of these strips were bio-assayed with the results shown in Table II-5.

TABLE II-5. B. Stearothermophilus Test Specimen Assay

	Counted Population	
	Non Heat Shocked	Heat Shocked
Specimen No.	Actual Count	Actual Count
1	2.5×10^6	1.3×10^6
2	4.2×10^6	1.1×10^6
3	1.9×10^6	1.3×10^6
4	2.4×10^6	0.7×10^6

Part of the problem of higher assay counts may be due to the characteristic difficulty in heat activating B. stearothermophilus. The counts obtained do not necessarily represent the true number of viable spores present, but represent only the number which were susceptible to the initial heat shock activation.

TASK 4. FULL SCALE FACILITY DESIGN STUDY

The design study for the full scale study has been continued during this quarter at a significantly reduced level of effort. Because of the necessary extension of the program to accomodate the test program delay, the facility design study has been streched out so that the test program experience can be factored into the final phase of the study.

II-2 FACILITY DEVELOPMENT (A/S ANALOG)

The Facility Development effort was completed in the fourth program quarter. The continuing effort on the analog has resulted from system difficulties and is discussed in section IV.

SECTION III

ACTIVITY PLANNED FOR NEXT QUARTER

ACTIVITY PLANNED FOR NEXT QUARTER

The [illegible]ter's activity will consist of essential completion of the [illegible] on the program. The test program task 2 should be [illegible] of task 3 should be completed, except for incubation assay samples from the last test demonstration cycle, and the [illegible]should be complete.

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SECTION IV

PROBLEM AREAS

IV. PROBLEM AREAS

There have been two problems of considerable significance this quarter: Main Chamber blower inadequacy and ETO/Freon concentration in decontamination cycles.

IV-1 MAIN CHAMBER BLOWER

During the first attempted sterility verification cycle, the main chamber blower began to overload as the ETO/FREON was purged into the system. Before the concentration reached the required level, the motor protectors kicked-out and the motor could not be brought back on line and be kept operating. Thus, during this cycle the gas was not circulated in the main chamber, Follow-up on this problem has indicated that the blower supplier neglected the high density of ETO/FREON in motor application analyses.

G.E. tried several "quick fixes" to reduce the gas flow rate in the main chamber in an attempt to bring motor load within safe operating limits for the ETO/FREON mode. It was not possible to make sufficient reduction in flow to achieve this objective.

As an alternative approach, G.E. has investigated the possibility of resuming the test program with use of ETO/FREON in the auxiliary chamber only. In this plan, all decontamination would be done in the auxiliary chamber - a condition of operation which, in fact, better simulates the operational plan suggested by the gas economics analysis of the Full Scale Study. This approach was discussed with the NASA/LRC technical representative and verbal concurrence was given. The subsequent successful sterility verification cycle was performed on the basis of this revised plan.

A new, larger capacity blower/motor combination has been received by GE for installation in the analog. However, at this time it is not intended to disrupt the test program to install the motor/blower unless the existing equipment demonstrates further deficiencies.

IV-2 ETO/FREON GAS CONCENTRATION

In the performance of system checkout and the aborted and successful sterility verification cycle, an ETO/FREON environment has been established in the analog several times. Analyses of the concentration of the gases by chromotography has indicated difficulty in establishing proper gas concentrations. The specific difficulties have been:

1. Indications of excess air present in the system.

2. Indications of an improper relative concentration of ETO/FREON.

These problems have been and continue to be under analysis. The tentative findings are:

1. Excess air concentrations appear to be due to sampling technique deficiencies. One set of gas analyses made after modification of the sampling technique has yielded much better results.

2. ETO/FREON relative concentrations which have ranged from extreme ETO depletion to significant ETO enrichment of the ETO/FREON gas mix appear to be due to the implementation of the liquid to gas conversion in the analog possibly complicated by gas sampling/analysis difficulties. The liquid to gas conversion equipment is being reworked, and this is expected to eleminate this source of difficulty. The sampling/analysis technique is under review to identify and correct any deficiencies in this area.

It should be noted that even with the gas concentration problems a second sterility verification cycle, under way at the end of the quarter, but completed by the time of preparation of this report, has indicated excellent ETO/FREON decontamination in the analog auxiliary chamber.